DGH TECHNOLOGY, INC.

510(k) Summary

APR - 5 2010

(21 CFR 807.92(c))

510(k) K093371

Submitter: DGH Technology, Inc.
110 Summit Drive, Suite B
Exton, PA 19341

Contact Person: M. Luther Detweiler
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Affairs and Quality Assurance

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Date Summary Prepared: March 12th, 2010

Device Trade Name: DGH 6000 Scanmate A.

Device Common Name: Ultrasound A-Scan biometer.

Device Classification:

Device: System, Imaging, Pulsed Echo, Ultrasonic
Panel: Radiology
Product Code: IYO
Device Class: II
Regulation Number: 21 CFR 892.1560

Device: Diagnostic Ultrasonic Transducer
Panel: Radiology
Product Code: ITX
Device Class: II
Regulation Number: 21 CFR 892.1570

DGH TECHNOLOGY, INC.

Legally Marketed Predicate Device(s):

DGH 3000A Ultrasonic A-Scan (K872726)
Quantel Medical AXIS II Ultrasonic Biometer (K000554)

Description of Device:

The DGH 6000 A-Scan is a USB plug-in device that uses A-Mode, pulsed echo ultrasound technology to measure the axial length (AL), anterior chamber depth (ACD), and lens thickness (LT) of the human eye. The device includes formulas to calculate the implanted IOL power, using the axial length measurement.

Intended Use of the Device:

The intended use of the DGH 6000 is the measurement of AL, ACD, LT of the human eye. The DGH 6000 is also intended to calculate the optical power of an IOL that is to be implanted during cataract surgery. The DGH 6000 is intended to be used solely by qualified medical professionals. Clinical consideration and judgment should be applied when using the DGH 6000.

Technological Characteristics:

Axial length (AL), anterior chamber depth (ACD), and lens thickness (LT) measurements are obtained using the same technology as the predicate device, DGH 3000A. The technology is based on ultrasonic pulse echo technology, whereby short bursts of ultrasonic energy are transmitted and the resulting echoes are captured, amplified, filtered and processed. Specific time distances in the captured echo peaks are then measured and converted into distance information. Digital signal processing algorithms validate individual peaks and proper probe alignment. The resulting measurements and waveforms are then displayed on a PC monitor for the medical (ophthalmic) professional user. In addition, the software assists the user in calculating replacement intraocular lens values based on established IOL calculation formulas.

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DGH TECHNOLOGY, INC.

Performance Tests:

The following tests were performed to demonstrate substantial equivalence:

(A) Non-Clinical Tests

- Comparative test block (phantom) tests
- EN 60601-1:1990 Medical Electrical Equipment Part 1 General Requirements for Electrical Safety
- EN 60601-1-2:2002 Medical Electrical Equipment Collateral Standard: Electromagnetic Compatibility
- NEMA Standard Publication UD-2 2004: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA Standard Publication UD-3 2004: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

(B) Clinical Tests

Since the DGH 6000 Scanmate-A uses the same technology as existing devices, clinical tests are not required.

Conclusions:

We have reviewed the results of the performance tests and have determined that the DGH 6000 is substantially equivalent, in safety and efficacy, to the legally marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 5 2010

DGH Technology, Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K093371
Trade/Device Name: DGH 6000 Scanmate A
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 23, 2010
Received: March 24, 2010

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DGH 6000 Scanmate A, as described in your premarket notification:

Transducer Model Number

DGH 6000

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K093371

Device Name: DGH 6000 Scanmate A

Indications for Use: The intended use of the DGH 6000 is the measurement of AL, ACD, LT of the human eye. The DGH 6000 is also intended to calculate the optical power of an IOL that is to be implanted during cataract surgery. The DGH 6000 is intended to be used solely by qualified medical professionals. Clinical consideration and judgment should be applied when using the DGH 6000.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K093371

Attachment 3

Indications for Use Form

510(k) K093371
System: DGH 6000 Scanmate A
Transducer: DGH 6006

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**A-Mode**
Ophthalmic	Ophthalmic							P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

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Indications for Use Form

510(k) K093371
Transducer: DGH 6006

Intended Use: The intended use of the DGH 6006 transducer is the measurement of AL, ACD, LT of the human eye. The DGH 6006 transducer is intended to be used solely by qualified medical professionals. Clinical consideration and judgment should be applied when using the DGH 6006 transducer.

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**A-Mode**
Ophthalmic	Ophthalmic							P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

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